K132040

8. 510(K) SUMMARY

JUL 3 1 2013

Device: Vial Connector 13 mm Closed Collar

Company Name:

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Preparation date: 25 June 2013

Classification:

Classification Name:	IV Administration Set
Trade Name:	Vial Connector 13 mm Closed Collar
Common/Usual Name:	Vial Connector 13 mm Closed Collar
Product Code:	LHI
Regulation No.:	880.5440
Class:	II
Panel Identification:	General Hospital Panel

Predicate Devices: Mixject Dispensing Pin from Medimop Medical Projects, Ltd, cleared by 510(k) number K963583 and K001293

Device Description:

The proposed device, Vial Connector 13 mm Closed Collar, is intended for use in healthcare facilities or in home environment by the patient or care-giver to aid and support prescribed treatment and therapy.

The proposed device consists of two integrated parts, the first part is the 13mm vial connector body intended to be attached to a standard 13 mm drug vial neck and a male luer connection. The vial connector body contains the single lumen piercing spike and an assembled 5µm fluid path filter (Versapor® Hydrophilic membrane on a HDPE disc). The second part of the device is the closed collar which restricts the connection of the vial connector to standard 13 mm vials with a body diameter of up to 15 mm. The two integrated parts are injection molded as one single device. The proposed device does not contain any medicinal substances.

Indications for use:

The proposed device is indicated for the transfer and mixing of drugs contained in a vial.

Substantial equivalence

The proposed device, Vial Connector 13 mm Closed Collar, has the same indications for use and principle of operation as the predicate device, Mixject Dispensing Pin, from Medimop Medical Projects, Ltd, cleared by 510(k) number K963583 and K001293, and is therefore substantially equivalent to the predicate device.

Conclusion

The evaluation of the proposed device, Vial Connector 13 mm Closed Collar, does not raise any additional concerns regarding safety and effectiveness and may therefore be considered substantially equivalent to the predicate device, Mixject Dispensing Pin, 510(k) K963583 and K001293.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 31, 2013

Medimop Medical Projects, Ltd
Mr. Ilanit Goldgraber
Director of Regulatory Affairs
17 Hatidhar Street
RA'ANANA ISRAEL 4366519

Re: K132040
Trade/Device Name: Vial Connector 13mm Closed Collar
Regulation Number: 21 CFR 880.5440
Regulation Name: Set, I.V. Fluid Transfer
Regulatory Class: II
Product Code: LHI
Dated: June 25, 2013
Received: July 5, 2013

Dear Mr. Goldgraber:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

7. INDICATIONS FOR USE

510(k) Number (if known): K132040

Device Name: Vial Connector 13 mm Closed Collar

Indications for Use:

The proposed device is indicated for the transfer and mixing of drugs contained in a vial.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K132040

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Richard C. Chapman
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